

Listing of Claims

1. (Previously presented) A controlled release pharmaceutical tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises nimesulide as an active drug upto 99% w/w of the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition, said nimesulide being present in the fast release layer and in the extended release layer.
2. (Previously presented) The controlled release pharmaceutical tablet composition of nimesulide as claimed in claim 1 wherein the nimesulide as an active drug is from 20% to 70% w/w of the tablet composition, the one or more release controlling materials are from 5% to 65% w/w of the tablet composition and the pharmaceutical excipients are from 10% to 70% w/w of the tablet composition.
3. (Cancelled)
4. (Previously presented) The controlled release pharmaceutical tablet composition of nimesulide as claimed in claim 1, wherein the one or more release controlling materials are selected from the group consisting of cellulose and cellulose derivatives, waxes, carbomers, polyalkylene polyols, polycarbophils, methacrylic acid copolymers, gelatins, gums and polyethylene oxides.
5. (Currently Amended)The composition as claimed in claim 1, wherein the fast release release layer, the extended release layer or both further comprise one or more release modifiers selected from the group consisting of wetting agents, solubilizers, surfactants, plasticizers, pore formers, pH modifiers and tonicity adjusting agents.

6. (Cancelled)

7. (Cancelled)

8. (Previously presented) The tablet composition as claimed in claim 1, wherein the extended release layer further comprises polymers, selected from the group consisting of polycarbophils, carbomers, alginates, cellulose and cellulose derivatives, chitosan gums and lectins.

9. (Previously presented) The tablet composition as claimed in claim 1, further comprising in the fast release layer, extended release layer or both pharmaceutically acceptable materials selected from the group consisting of sodium bicarbonate, sodium carbonate, calcium carbonate and potassium carbonate alone or in combination with an acidic substance selected from the group consisting of hydrochloric acid, citric acid, fumaric acid, malic acid, maleic acid, ascorbic acid and tartaric acid.

10. (Previously presented) The tablet composition as claimed in claim 1, further comprising in the fast release layer, extended release layer or both, material selected from the group consisting of fats, fatty acids and transesterification products of fats and fatty acids with polyols.

11. (Previously presented) A process for the manufacture of a controlled release tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises mixing together nimesulide as an active drug up to 99% w/w of the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition said nimesulide being present in the fast release layer and in the extended release layer.

12. (Cancelled)

13. (Cancelled)

14. (Cancelled)

15. (Previously presented) The controlled release pharmaceutical tablet composition of nimesulide as claimed in claim 2 wherein the one or more release controlling materials are selected from the group consisting of cellulose and cellulose derivatives, waxes, carbomers, polyalkylene polyols, polycarbophils, methacrylic acid copolymers, gelatins, gums and polyethylene oxides.

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Previously presented) The composition according to claim 1 wherein the fast release layer comprises nimesulide and one or more pharmaceutical excipients selected from diluents, binders, wetting agents, disintegrants and lubricants; and the extended release layer comprises nimesulide and release controlling material.

20. (Cancelled)

21. (Cancelled)

22. (Cancelled)

23. (Cancelled)

24. (Cancelled)

25. (Previously presented) A controlled release pharmaceutical tablet composition for peroral administration consisting of a coating, a single unit fast release layer and single unit extended release layer which comprises nimesulide as an active drug upto 99% w/w of the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition, said nimesulide being present in the fast release layer and in the extended release layer.

26. (Previously presented) A controlled release pharmaceutical tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises nimesulide as an active drug upto 99% w/w of the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition, wherein the fast release layer comprises nimesulide, lactose, starch, colloidal silicon dioxide, polyvinylpyrrolidone, polyoxyethylene sorbitan monostearate, docusate sodium, magnesium stearate and croscarmellose sodium; and the extended release layer comprises nimesulide, lactose, polyvinylpyrrolidone, magnesium stearate, docusate sodium, hydroxypropyl methylcellulose, colloidal silicon dioxide and sodium lauryl sulphate.

27. (Previously presented) A controlled release pharmaceutical tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises nimesulide as an active drug upto 99% w/w of the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition, wherein the fast release layer comprises nimesulide, lactose, starch, colloidal silicon dioxide, polyvinylpyrrolidone, polyoxyethylene sorbitan monostearate, docusate sodium, magnesium stearate and croscarmellose sodium.

28. (Previously presented) A controlled release pharmaceutical tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises nimesulide as an active drug upto 99% w/w of

the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition, wherein the extended release layer comprises nimesulide, lactose, polyvinylpyrrolidone, magnesium stearate, docusate sodium, hydroxypropyl methylcellulose, colloidal silicon dioxide and sodium lauryl sulphate.

29. (Previously presented) A controlled release pharmaceutical tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises nimesulide as an active drug upto 99% w/w of the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition, wherein the fast release layer comprises nimesulide, polyvinylpyrrolidone, magnesium stearate and croscarmellose sodium.

30. (Previously presented) A controlled release pharmaceutical tablet composition for peroral administration consisting of a single unit fast release layer and a single unit extended release layer which comprises nimesulide as an active drug upto 99% w/w of the tablet composition, one or more release controlling materials from 0.1% to 99% w/w of the tablet composition and pharmaceutical excipients from 0% to 90% w/w of the tablet composition, wherein the extended release layer comprises nimesulide, polyvinylpyrrolidone, magnesium stearate and hydroxypropyl methylcellulose.